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EXAMINER

BAKER, MAURIE GARCIA

ART UNIT PAPER NUMBER

1639

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary

Application No.
09/839,469

Applicant
Huse et al

Examiner
Maurie G. Baker, Ph.D.

Art Unit
1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Aug 19, 2002

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-9 is/are pending in the application

4a) Of the above, claim(s) _____ is/are withdrawn from consideration

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-9 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413) Paper No(s). _____

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) ☐ Notice of Informal Patent Application (PTO-152)

3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3

6) ☐ Other: _____

DETAILED ACTION

Please note: The number of Art Unit 1627 has been changed to 1639. Please direct all correspondence for this case to Art Unit **1639**.

1. The Response filed on August 19, 2002 (Paper No. 7) is acknowledged. No claims were cancelled, added or amended in this response. Therefore, claims 1-9 are pending.

Election/Restriction

2. The Restriction Requirement is moot in view of the previous cancellation of claims 10-38. Applicant's election of species is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the requirement, the election has been treated as an election without traverse with respect to the species (MPEP § 818.03(a)).

3. Therefore, claims 1-9 are examined on the merits in this action.

Specification

4. The specification is objected to for the following matter:

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2).

However, this application fails to comply with the requirements of 37 CFR 1.821 through

1.825 because it lacks the notations of "SEQ. ID NO. ____" next to the sequences. See, for example, Table I on pages 53-54 of the specification. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. Applicant's claims are directed to a method of determining binding of a "receptor" to one or more "ligands". The claims use generic terminology such as "collective receptor variant population",

“binding activity” and “optimal binding affinity”. These terms are defined in the instant disclosure but the definitions are very broad.

The language of the specification should describe the claimed invention so that one skilled in the art can recognize what is claimed. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *University of California v. Eli Lilly and Co.* (U.S. Court of Appeals Federal Circuit (CAFC) 43 USPQ2d 1398 7/22/1997 Decided July 22, 1997; No. 96-1175).

The specification discloses very limited and mostly prophetic examples of carrying out the claimed method. The claimed receptors and ligands could encompass very different moieties such as peptides, oligonucleotides or other organic molecules. Also, claims 6 and 7 require specific techniques of producing the ligands (recombinant expression in melanophore cells) and claim 9 requires tagging. None of these techniques are adequately described in the instant disclosure.

Thus, the disclosure simply does not provide adequate support to show possession of the claimed invention. The disclosure is neither representative of the claimed genus, nor does it represent a substantial portion of the claimed genus. Moreover, the claimed genus encompasses members which are yet to be prepared or envisioned. This further evidences that instant disclosure does not constitute support for the claimed genus or a substantial portion thereof.

7. Claims 1 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”. These factors can include, but are not limited to:

- (1) the breadth of the claims;
- (2) the nature of the invention;
- (3) the state of the prior art;
- (4) the level of one of ordinary skill;
- (5) the level of predictability in the art;
- (6) the amount of direction provided by the inventor;
- (7) the existence of working examples; and
- (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The breadth of the claims and the nature of the invention: The claims are drawn to a method of determining binding of a “receptor” to one or more “ligands”. No limitations on the specific structure of the ligand or receptor are given and, as such, this could read on a wide variety of structures. The invention is such that each of the components must be present in operable form for successful practice of the invention. For example, the receptor must bind the ligand and the binding must be able to be detected. Claim 9 specifically requires that the receptor variant is “linked to an identifiable tag”. The state of the prior art and the level of predictability in the art: Ligand/receptor binding pairs were well-known in the art

at the time of the invention (see art rejections below); however, only limited numbers of such pairs were known and the specification gives no guidance to permit one of skill in the art to devise strategies for synthesis of *any* such pair of molecules. The structures of possible variants are sufficiently diverse that one of ordinary skill would not be able to predict their structures with respect to the linking of the receptor variant to an “identifiable tag”. The examiner’s position is that the art is not predictable to the point that one of ordinary skill could make and use the invention as claimed. Note that the “predictability or lack thereof” in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. With regard to claim 9, adding tags to the receptors adds to the unpredictability of the claimed method since this type of synthesis requires high efficiency and is further complicated by carryover, cross-reactions, etc., all of which are acknowledged issues in the art. Each must be dealt with in the optimization of a synthesis scheme. A review article published by Janda discusses these issues (see Proc. Natl. Acad. Sci. 1994; on PTO-1449. See especially page 10782-10785). The level of one of ordinary skill: The level of skill would be high, most likely at the Ph.D. level. However, such persons of ordinary skill in

this art, *given its unpredictability*, would have to engage in undue (non-routine) experimentation to carry out the invention as claimed. The existence of working examples and the quantity of experimentation needed to make or use the invention based on the content of the disclosure: Applicants have provided no specific examples of the claimed method where the receptors are tagged, especially with respect to imparting and decoding the information present in an “identifiable tag” for any receptor. Thus, it is the examiner’s position that the instant specification does not provide to one skilled in the art a reasonable amount of guidance with respect to the direction in which the experimentation should proceed in making and using the claimed invention. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 & n.23 (Fed. Cir. 1991). Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the invention as claimed.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites that the receptor variants have “optimal binding activity”. The term “optimal” is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is simply unclear what binding criteria would qualify as “optimal”.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Lerner et al (US 5,462,856; on PTO-1449).

Lerner et al disclose a method for identifying a chemical that acts as an agonist for a G-protein coupled cell surface (GPC) receptor (see Abstract). The method uses expression of the receptors in pigment cells, specifically melanophores (see, for example, column 13, lines 54-67; Example 6 in columns 17-19 and patented claims 9-10). Lerner et al disclose a multiplicity of GPC receptors that are expressed, see, for example, column 14, lines 31-49 and column 15, lines 3-11. The reference clearly teaches “cloning new GPC receptors” (see

column 15, lines 17-22; and patented claims 9-10; for example); this reads directly on the claimed “collective receptor variant population”. Lerner et al teaches a variety of bioassays that can be used to screen the GPC receptors for binding to ligands (see Examples 1-5 in columns 15-17); this reads directly on the “contacting” and “detecting” steps of the claimed method. The reference also discloses a procedure for isolating a clone for a GPC receptor via a fractionation procedure (see column 18, line 65 – column 19, line 11). Specifically disclosed is a procedure where colonies are tested, then can be subdivided into smaller pools (such as 10 sets of 1,000 colonies each from a pool of 10,000) based on positive results where each sub-set is retested until a single clone is identified. This reads directly on the “dividing, contacting and detecting” steps of instant claims 2, 3 and 8 and the identification steps of instant claims 4 and 5.

Status of Claims/Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
November 18, 2002

A handwritten signature in black ink, appearing to be 'MB' followed by a long horizontal stroke.

MAURIE GARCIA BAKER, Ph.D.
PATENT EXAMINER